



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, Fl 32751

WARNING LETTER

FLA-99-69

June 8, 1999

Dr. Jonah S. Botknecht  
President, Medical Research  
Industries, Inc.  
3101 S.W. 10<sup>th</sup> Street  
Pompano Beach, Florida 33069-4800

Dear Dr. Botknecht:

This letter is in reference to your firm's marketing and distribution of the products, SlimPatch, 911Patch, StressPatch, and SleepPatch. Labeling for these products contains therapeutic claims which cause the products to be drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

Examples of the objectionable claims include:

SlimPatch .....help in weight loss and control

911Patch .....relieve between meal hunger cravings

StressPatch .....relieve stress related anxiety

SleepPatch .....induce sound and restful sleep

In addition, these products are labeled as homeopathic and are transdermal because they are intended to have a systemic effect on the body and are "intended to effectively bypass the digestive system's acids and enzymes." Transdermal delivery systems, including "liposomal" delivery systems, are not recognized by the homeopathic community as valid homeopathic dosage forms. In 1989, the Agency made a determination that

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transdermal delivery systems are not homeopathic and are new drugs based on the newness of the delivery system [Title 21, Code of Federal Regulations (21 CFR), section 310.3].

SlimPatch, 911Patch, StressPatch, and SleepPatch are "new drugs" [section 201(p) of the Act]. Therefore, they may not be legally marketed in this country without approved New Drug Applications [section 505(a) of the Act]. They are misbranded because their labeling fails to bear adequate directions for the condition for which they are offered [section 502(f)(1) of the Act]. Their labeling is also false and misleading, since it suggests that the products are safe and effective for their intended uses when this has not been established [section 502(a) of the Act].

The drugs are also adulterated [section 501(a)(2)(B) of the Act] in that the methods used in, and the facilities and controls used for, their manufacture, processing, packing or holding do not conform to or are not administered in conformity with current good manufacturing practice (GMP) regulations [21 CFR, Part 211] as follows:

No component testing; inadequate process validation or cleaning validation; no expiration dates listed on the labels; inadequate label controls; no written procedures for maintenance or calibration of equipment; and, failure to follow written complaint procedures.

Further, we are aware that these products are also promoted on your firm's Internet web site. This site also discusses a number of proposed "Patch" products intended for depression, motion sickness, allergies, arthritis, smoking cessation, PMS, hair loss, and as an alternative to Viagra. If these products are transdermal then they will also be "new drugs"

This letter is not intended to be an all inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and

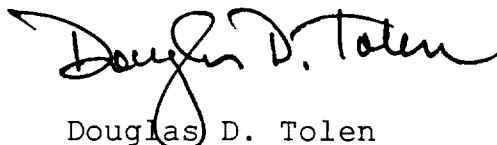
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Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Martin E. Katz, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4729.

Sincerely,

A handwritten signature in black ink, reading "Douglas D. Tolen". The signature is fluid and cursive, with a large loop at the end of the last name.

Douglas D. Tolen  
Director, Florida District